Cancer Prevention Among Working Class, Multiethnic Adults: Results of the Healthy Directions–Health Centers Study

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Objectives. We analyzed outcomes from a study that examined social-contextual factors in cancer prevention interventions for working class, multiethnic populations.

Methods. Ten community health centers were randomized to intervention or to control. Patients who resided in low-income, multiethnic neighborhoods were eligible; the intervention targeted fruit and vegetable consumption, red meat consumption, multivitamin intake, and physical activity. Outcomes were measured at 8 months.

Results. The intervention led to significant increases in fruit and vegetable consumption and multivitamin intake and reductions in red meat consumption; no change was found in physical activity levels. The intervention effect was not changed when contextual variables that may function as confounders or effect modifiers (e.g., gender, education, race/ethnicity, respondent and parents' country of birth, and poverty status) were included in the analyses.

Conclusions. The intervention led to significant improvements in health behaviors among a working class, multiethnic population, regardless of race/ethnicity and socioeconomic status. Interventions that respond to the social context of working class individuals across racial/ethnic categories hold promise for improving cancer-related risk behaviors. (*Am J Public Health.* 2005;95:1200–1205. doi:10.2105/AJPH.2004.038695)

Disparities in cancer morbidity and mortality rates by race/ethnicity and socioeconomic position have been well documented and are a key research priority.[1,2] Across health behaviors, patterns of risk by socioeconomic position remain constant: persons of higher socioeconomic position engage in fewer high-risk behaviors than do persons of lower socioeconomic position.[3–5] Similar patterns are found by race/ethnicity.[3,6–8]

The health care system is an important channel for reducing behavioral risk factors among diverse populations.[9–11] Brief physician counseling has been found to be effective with diet and tobacco use,[12–15] although evidence is currently inconclusive regarding the effect of provider counseling on physical activity.[16,17] The rates of physicians providing behavior change counseling are quite low.[18,19] Adjuncts to brief provider counseling are effective,[17] and provider interventions may be more effective if patients are referred to other programs that provide ongoing social support.[10,20]

We present the outcome results of Healthy Directions–Health Centers, an intervention study designed to reduce cancer risk factors among working class, multiethnic populations seen in community health centers. This study was part of the Harvard Cancer Prevention Program Project, the theme of which was to create cancer prevention interventions that are effective with working class, multiethnic populations. This program project was designed to develop and test behavioral interventions for multiple cancer risk factors in working class and ethnically diverse groups through 2 intervention channels: health centers and worksites.

The 2 intervention projects (Healthy Directions–Health Centers and Healthy Directions–Small Businesses) were randomized controlled trials that used the organization (e.g., health center or small business) as the unit of randomization and intervention and the individual as the unit of analysis. Both projects used a common conceptual model and intervention paradigm[21] and focused on common primary outcomes: fruit and vegetable consumption, red meat consumption, multivitamin intake, and physical activity. The design of the interventions was largely based on social epidemiological findings related to disparities in health behaviors and health outcomes. Healthy Directions was designed to take into account elements of the social context that are critical components of an ecological approach to health behavior change. We present the outcomes of the 8-month follow-up of the Healthy Directions–Health Centers project.

METHODS

Study Design

Healthy Directions–Health Centers was a randomized controlled trial in which the health center was the unit of randomization and intervention. Ten health centers were paired on membership size and randomized within pairs to the intervention condition or usual care; the health centers shared practice guidelines, practice style, and other systems factors that might have affected outcomes. Patients who resided in low-income, multiethnic neighborhoods were identified and approached for participation.

Setting

This study was conducted in collaboration with Harvard Vanguard Medical Associates, a health care delivery system composed of 14 multispecialty medical group practices that serve more than 270 000 patients. The 10 health centers that were invited to participate took part in the study.

Sample

Patient eligibility criteria included (1) living in an eligible neighborhood (discussed later in this paragraph), (2) being 18 to 75 years of age, (3) having a well-care or follow-up visit scheduled with a participating provider, (4) being able to speak and read either English or Spanish, (5) not having cancer at the time of enrollment, (6) not being employed by the participating health centers, and (7) not being employed at a worksite

participating in the companion study. Eligible neighborhoods were defined according to census definitions to be census block groups that were predominantly working class (66% or more of the employed persons are in working class occupational groups) or impoverished (20% or more of the population lives below the poverty level) or with low levels of education (25% or more of the adult population has not completed high school).

All providers practicing in the internal medicine departments of these centers were approached for permission to recruit from among their patient pools. Provider participation averaged 83% across sites (range= 50%–100%); a total of 97 clinicians participated, with no differences in clinician participation between the 2 study conditions.[22] All participating providers received brief training (1 hour) during a regular staff meeting about the study design, intervention messages (intervention sites only), and an implementation plan.

Patients who were scheduled for appointments with the participating providers and were in the eligible age range were identified through the automated central appointment system. Geocoding was used to determine whether a potential participant lived in an eligible neighborhood, assessed at the census block group level.[23,24] Eligible patients residing in the target census block groups with an appointment no sooner than 2 weeks after identification received a letter in the mail describing the study and giving them the opportunity to request no further contact. Patients were then contacted by telephone where eligibility was confirmed, an invitation to participate was extended, and the baseline survey was completed.

Study staff attempted to recruit 8963 potentially eligible candidates. Of these attempts, 2547 (28%) were unreachable, 867 (10%) were ineligible, 3330 (37%) refused, and 2219 (25%; 40% of those reached and eligible) were enrolled. The cohort recruited at baseline was contacted by telephone after the intervention period to complete a follow-up survey. Of the 2219 who completed the baseline survey (n=1088 intervention condition; n=1131 control condition), 1954 (88%) completed the follow-up survey. Follow-up response rate was equivalent across conditions.

Intervention Components

The intervention is described in detail elsewhere[25] and is summarized here. The intervention used a social-contextual approach targeting multiple levels of influence on behaviors, with special attention to low literacy skills and the shared and unique features of culture across racial/ethnic groups.[21,25] We drew heavily on the social epidemiology literature to broaden the intervention beyond the standard behavioral and psychological theoretical literature and to consider societal factors that may influence health behavior in the intervention design.

The intervention activities and materials included strategies, images, messages, and vocabulary that were inclusive and nonstereotyping for the multicultural audiences and that used tactics to reach participants with limited literacy skills (e.g., plain language, simple graphics, stories). Project messages explicitly acknowledged that health behavior is influenced by context.

Only those participants who were patients in the health centers randomized to the intervention condition and who consented to be in the study received the intervention, which consisted of (1) study endorsement from the participant's clinician at a scheduled routine-care visit, including provision of a tailored prescription for the recommended health behavior changes; (2) an initial in-person counseling session with a health adviser; (3) 4 follow-up telephone counseling sessions with the health adviser; (4) 6 sets of tailored materials written for low-literacy audiences that targeted social contextual factors (e.g., family composition, available social support and networks, occupational status, neighborhood safety concerns); and (5) links to relevant local activities. Health advisers were college-educated individuals with substantial community experience, had diverse racial/ethnic and socioeconomic backgrounds, and were bilingual in Spanish.

The counseling used motivational interviewing as a strategy to contextualize the intervention and to enhance understanding of the factors that influenced a patient's motivation and ability to change.[26,27] This approach was particularly helpful when addressing concerns relevant to this multiethnic population while minimizing assumptions about factors related to participants' health behaviors. The in-person session was designed to be approximately 20 minutes in length, and the follow-up telephone calls were approximately 10 minutes in length. The intervention was developed with substantial input from a community advisory board, which ensured that the intervention was designed and implemented in accordance with community priorities and expectations.

Measures

Health behaviors. The National Cancer Institute's 5 A Day for Better Health Program screener was used to measure *servings of fruit and vegetables* consumed per day.[28] Responses were recoded to equivalent servings per day and summed to obtain total fruit and vegetable servings per day. We then computed a dichotomous measure: 5 or more servings per day or fewer than 5 servings per day.

Red meat consumption was assessed with an abbreviated form of the semiquantitative Food Frequency Questionnaire.[28] The responses were recoded to equivalent servings per week and summed to obtain total servings of red meat per week. The totals were dichotomized to 3 or fewer servings or more than 3 servings per week.

Physical activity was assessed based on the questionnaire used in the Nurses' Health Study,[29] adapted to include specific activities that were common in our target population. The questionnaire asked how often in the last 4 weeks respondents engaged in each activity, on average. Responses were recoded to equivalent minutes per week and summed to obtain total minutes of physical activity per week. Walking was included in the total only if the walking pace was reported to be "normal/average" or faster. The total was collapsed to 150 minutes (2.5 hours) per week or more versus less than 150 minutes per week.

We asked respondents how many days, on average, they took a *multivitamin.* Responses were coded as daily if subjects reported taking a multivitamin 6 or 7 days per week.

Sociodemographic characteristics. Respondents were asked their date of birth, gender, and highest level of education completed. They were asked to identify all the racial and ethnic groups to which they belonged. We coded participants who reported being of Hispanic or Latino origin in the Hispanic group regardless of any other ethnic groups

mentioned. Those who reported only 1 ethnic group were categorized in that group; respondents who selected more than 1 group (not including Hispanic) were classified as mixed heritage.

Household income was assessed in 5 categories (<$10 000 per year to $50 000 or more). We combined the responses to this item with the number of people supported by the income and compared it with the federal poverty guidelines.[30] On the basis of this information, subjects were classified as (1) below the poverty guideline, (2) above the poverty guideline but below 185% of the guideline, or (3) above 185% of the poverty guideline.

We combined information about the participants' and their parents' birthplaces into a 3-category measure: (1) participant born outside the United States; (2) participant born in the United States, but 1 or more parents born outside the United States; or (3) participant and both parents born in the United States. We combined information about the respondent's employment status and job title into a 3-category job-status variable: (1) employed in a blue-collar job, (2) employed in a job that is not blue collar, or (3) unemployed or retired.

Costs. A process tracking system was developed to collect detailed data on all costs associated with the intervention delivery. Staff and health adviser time were valued at actual salary rates, including fringe benefits. Telephone use was valued at $0.07 per minute. All other resources were valued at their actual invoice costs. The per-subject baseline survey cost was estimated by dividing the total survey cost by the number of subjects; the proportion of the survey required for generating the tailored intervention reports was derived by prorating the costs by the percentage of the survey devoted to the collection of information for tailoring (42% of survey questions). This is likely an overestimate of costs because some of this information would be required for intervention evaluation irrespective of tailoring.

Data Analysis

In all analyses, we controlled for the clustering of respondents in the randomization unit—health centers. To assess the effectiveness of the intervention, we analyzed each outcome measure separately and in the binary scale. We computed a repeated-measures, mixed-model logistic regression analysis with the intervention group and survey (baseline or follow-up) as fixed effects and the health center as a random effect.[31] The participant was included as a repeated random effect within the randomization unit in the intervention condition. This method incorporates cases with missing data, as long as the data are missing at random.[32] The test of hypotheses of no difference in change in behavior between intervention and control conditions was examined by the interaction effect of intervention group by survey. We used the coefficients from the linear logistic regression model to compute the adjusted percentages. To carry out the analyses, we used the GLIMMIX macro to the SAS statistical software (SAS Institute Inc, Cary, NC). This macro uses iteratively reweighted likelihoods to fit a logistic regression model in which the subjects are clustered in the random effect.[33]

To explore analyses of the target subgroups and to control for factors that may have been unbalanced despite randomization, we added covariates to the logistic regression analysis. Per-subject incremental costs were calculated by summing the costs for each group and dividing by the number of subjects randomized to that group.

RESULTS

Demographics

Table 1 presents the demographic characteristics of the sample by intervention condition.

TABLE 1—Frequency of Selected Characteristics at Baseline, by Randomization Group, With *P* Value for Test of Effectiveness of Randomization (N = 2219)

	Control		Intervention		
	Frequency	Adjusted,[a] %	Frequency	Adjusted,[a] %	*P*[b]
Gender					.08
Male	328	29.1	419	39.5	
Female	800	70.9	669	61.5	
Education					.61
≥ BA degree	448	40.6	394	38.2	
< BA degree	678	59.4	683	61.8	
Race/Ethnicity					
White, non-Hispanic	515	50.6	776	72.9	.15[c]
Black, non-Hispanic	398	27.4	181	15.4	.91[d]
Other	208	22.0	116	11.7	
Poverty, % of federal level					.09
> 185	902	81.6	912	85.3	
< 185	207	18.4	157	14.7	
Birth country					.95
Both parents and subjects born in United States	687	60.4	649	60.0	
Other	442	39.9	433	40.0	
Occupational class					
Unemployed	124	11.0	122	11.2	.86[e]
Working class	522	46.1	463	42.5	.14[f]
Professional/manager	485	42.9	503	46.3	
Age, adjusted mean		47.8		50.8	.18

[a] Percentages adjusted for clustering of respondents in health centers.
[b] *P* value for test of equality of group percentages, controlling for clustering of respondents in health centers.
[c] *P* value for test of equality of percent White, non-Hispanic vs percent Black, non-Hispanic and "other."
[d] *P* value for test of equality of percent Black, non-Hispanic vs percent "other."
[e] *P* value for test of equality of percent unemployed vs percentage employed.
[f] *P* value for test of equality of percent working class vs percentage professional/manager.

TABLE 2—Adjusted Percentages of Participants With Each Health Behavior at Baseline and Follow-Up, by Intervention Group (N = 1954)

		Control		Intervention		
	Survey	n	%	n	%	P^a
Servings of fruit and vegetables, ≥5/d						
	Baseline	982	14.8	953	13.9	
	Follow-up	979	11.0	959	17.2	
	Change		−3.8		+3.3	.005
Servings of red meat, ≤3/wk						
	Baseline	976	53.2	962	48.8	
	Follow-up	978	53.0	960	60.6	
	Change		−0.2		+11.8	<.001
Physical activity, ≥2.5 h/wk						
	Baseline	916	64.8	900	66.6	
	Follow-up	939	63.2	919	66.4	
	Change		−1.6		−0.2	.51
Multivitamins, ≥6 d/wk						
	Baseline	985	36.6	965	39.2	
	Follow-up	984	44.3	959	68.6	
	Change		+7.7		+29.4	<.001

[a]*P* value is for the test of the intervention × survey interaction (control vs intervention).

No significant differences in the demographic characteristics evaluated were seen between participants in the intervention and participants in the control health centers (Table 1).

Treatment Outcomes

We evaluated the effect of the intervention on health behavior by examining whether participants met the criterion for having the risk factor (e.g., if they ate fewer than 5 servings of fruits and vegetables per day, they were considered at risk for that variable). Table 2 presents the percentages of participants who reported the target values of the outcome variables according to the risk factor criteria.

Significantly greater change was found among participants in intervention health centers in fruit and vegetable consumption (P=.005), red meat consumption (P<.001), and multivitamin intake (P<.001). No significant differences were found in physical activity. These data indicate that 3.3% of the intervention participants increased fruit and vegetable consumption to at least 5 servings per day, whereas 3.8% of the control participants decreased consumption to below this level over the study period. Twelve percent of the intervention participants reduced red meat consumption to 3 or fewer servings per week, compared with no change in the control participants, and 29% of the intervention participants began daily multivitamin intake, compared with 8% of the control participants.

We also evaluated the effect of the intervention on fruit and vegetable intake, red meat intake, and physical activity—represented as continuous variables (Table 3)—receiving similar results to those found with the dichotomous measure. Overall, a 0.3 serving-per-day average increase in fruit and vegetable consumption occurred in the intervention group, and a 0.6 servings-per-week average decrease of red meat consumption was reported.

Covariate Analyses

We investigated each of the following covariates as potential confounders or effect modifiers: gender, education, race/ethnicity, respondent's and parents' birth country, and poverty status. No confounding effect of any variable was found. Controlling for these variables did not change the intervention effect for any of the behavioral outcomes. No significant effect modification occurred for any variable considered: none of the 3-way interaction effects was statistically significant.

Intention-to-Treat Analysis

To evaluate the effect of attrition on outcomes, we computed an intention-to-treat analysis by assuming that those study participants who did not complete the follow-up survey did not change any of the outcome behaviors from baseline. When we included the nonrespondents in the analysis, the results were almost identical to those computed for the respondents with complete data only.

TABLE 3—Adjusted Means for Health Behaviors at Baseline and Follow-Up, by Intervention Group[a] (N = 1954)

		Control		Intervention	
	Survey	Mean	SE	Mean	SE
Servings of fruit and vegetables per day					
	Baseline	3.19	0.062	3.28	0.062
	Follow-up	3.13	0.064	3.57	0.064
	Change	−0.04		+0.29	
Servings of red meat per week					
	Baseline	3.89	0.16	3.75	0.17
	Follow-up	3.97	0.17	3.14	0.17
	Change	+0.08		−0.61	
Hours of physical activity per week					
	Baseline	4.93	0.16	4.80	0.16
	Follow-up	4.91	0.16	4.77	0.17
	Change	−0.02		−0.03	

[a]Adjusted for clustering of patients in health centers.

Costs

The total intervention delivery cost per patient in the intervention arm was $168. Staff time related to intervention delivery was 67% of these costs. Nonresearch costs were not incurred for patients in the control arm; therefore, the incremental cost of the intervention was $168 per patient.

DISCUSSION

We have shown that a tailored intervention that incorporated aspects of the social context led to significant improvements in behavioral risk factors for cancer among low-income patients receiving care in a health care system that serves multiethnic populations. Effects were largest for multivitamin use and substantial for both red meat and fruit and vegetable consumption, whereas physical activity did not change. Effectiveness was comparable across subgroups defined by ethnicity and income, which is highly significant given the substantial evidence in the literature that health behavior change interventions are often less effective for underserved populations. The intervention was embedded in the health care system, but we used clinicians only to endorse the behavior changes being recommended; we then added several other intervention strategies to maximize the effect of the provider interaction. The intervention was well received by patients and providers and cost only $168 per patient.

The intervention produced the largest effect on multivitamin use, with almost 70% of the intervention participants taking a daily multivitamin at follow-up. The perceived relative "ease" of pill consumption should not undermine consideration of the importance of this outcome, because multivitamin use is strongly related to disease outcomes. Long-term use of folate-containing multivitamins has been associated with a 75% reduction in colorectal cancer mortality.[34] The change in multivitamin use seen in our study, if sustained, thus would be associated with as much as a 22% reduction in colorectal cancer incidence. Folic acid supplements also have been associated with lower rates of breast cancer[35] and reduction in morbidity related to cardiovascular disease, osteoporosis, and birth defects.[36,37]

At baseline, the sample had a relatively low level of fruit and vegetable consumption. Intervention participants increased their fruit and vegetable consumption by almost one third of a serving, whereas control participants reported a decrease in consumption. This level of change is similar to that found in worksite interventions,[38,39] although it is somewhat less than the effects found with health care interventions in health maintenance organization populations,[20,40,41] likely because of sample differences. The current study also yielded a significant reduction in red meat consumption compared with a slight increase in red meat intake in the control group. Few interventions have targeted red meat consumption, so it is not possible to compare this finding with those in other studies.

Physical activity did not change as a result of the intervention. The physical activity levels of the patients in this study were higher than expected by other estimates.[42] We conducted a validation study in which we compared self-reported minutes of physical activity with those measured on an actigraph activity monitor. The estimates of total activity (moderate plus vigorous) were very similar between the 2 methods. Within the context of a randomized controlled trial, the fact that the baseline physical activity levels were relatively high in both conditions did not influence our ability to examine the between-group differences in outcomes. However, future work will need to evaluate physical activity in similar populations in urban settings to learn more about specific sources of physical activity in lower-income groups and how to best capture these activities from an assessment perspective.

This study had several strengths. Health centers were the unit of randomization and analysis. The intervention targeted several risk factors concurrently, increasing its potential effects on cancer incidence and efficiency. The sample size was large enough to detect clinically important changes in health-related behaviors and to examine differences among subgroups defined by income and race/ethnicity. The cancer-related behaviors that were the targets of this study are also related to other diseases, which, taken together, account for a burden of suffering even greater than for cancer alone. The effects of the intervention are greater to the extent that the same behaviors underlie these other diseases.

Several limitations should be noted. Response rates ideally would have been higher; only 40% of the eligible patients participated, although participation did require a substantial effort on the patient's part. When participation in the intervention study was considered as an eligibility criterion, the response rate was considerably higher (62%). The study sample consisted predominantly of women and older participants (mean age=49). The results are only generalizable to similar populations. The intervention was implemented by health educators and would be feasible only in relatively large practices with substantial integration and structure, not in small groups with less extensive resources. However, these kinds of practices constitute much of US health care and are increasing in prevalence.

We recognize that this study included only short-term outcomes and that we did not provide evidence of long-term success. Future analyses also should address cost-effectiveness. However, the available data suggest that the Healthy Directions–Health Centers intervention is feasible in many health care settings and, if as effective in those settings, has the potential to produce changes in health-related behaviors that are large enough to be of public health and clinical importance. Because the Healthy Directions–Health Centers intervention was equally effective across individuals regardless of race/ethnicity and socioeconomic status, this study provides a step toward addressing the increasing disparities in cancer risk. ■

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Contributors

K.M. Emmons originated the study, served as principal investigator, supervised all aspects of study implementation, and oversaw article preparation. A.M. Stoddard served as study biostatistician and oversaw completion of the data analysis. R. Fletcher served as a co-investigator within the participating health care system and provided key input on study design and implementation related to the managed care environment. C. Gutheil was project director at Dana-Farber Cancer Institute and oversaw implementation of all aspects of the study design and evaluation. E.G. Suarez assisted with study implementation and supervision of project management staff and the health advisers. R. Lobb oversaw intervention delivery within the health care system and was responsible for provider training and on-site supervision of the health advisers. J. Weeks conducted the cost analyses. J.A. Bigby participated in the interpretation of the findings. All authors were involved in article preparation.

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Human Participant Protection

The research presented here was approved by the institutional review boards for Harvard School of Public Health and Harvard Medical School's Division of Ambulatory Care and Prevention.

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